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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3767	

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09/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/606,909	PETTIS ET AL.	
	Examiner	Art Unit	
	CATHERINE N. WITCZAK	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,10-13,15-24,29 and 32-39* is/are pending in the application.

4a) Of the above claim(s) *17-24 and 32-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,10-13,15,16 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/28/2008 and 2/29/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/28/2008 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 2-4, 10-13, 15, 16, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over GROSS (US Patent No. 5,848,991) or GROSS (US Patent No. 5,807,375) in view of PRAUSNITZ (US Patent No. 6,611,707), AUTRET, PURl (An investigation of the intradermal route as an effective means of immunization for microparticulate vaccine delivery systems), D'Antonio et al. (US Patent No. 6,056,716), SRIVASTAVA (US Patent No. 6,007,821), and The Merck Manual of Diagnosis and Therapy (17th ed.) (1999).

Gross '991 discloses a method of delivering various drugs, particularly insulin and hormones, intradermally (3:40-41; 6:56 - 7:20) using a single needle having a length from the housing of 300p.m - 3ram (4:10-35). This length would put the needle outlet at a depth within the

range of about 250gm - 2mm or 750gm - 1.5mm when the housing is set against a patient's skin to achieve ID delivery. Additionally, this depth would be required to meet the disclosure of Gross'991 to deliver the drugs intradermally. Gross '375 discloses a method of drug delivery using a needle that extends into the intradermal layer to deliver insulin into this intradermal layer (col. 5, line 25 - col. 6, line 34; col. 10, 11. 24-30, col. 14, 11.40-62). The needle length is chosen from the range 300gm - 3mm that extends from the housing to deliver into the intradermal layer at a depth of about 250p.m - 2mm or 750~tm - 1.5mm which is the depth of the intradermal layer (col. 10, 11.23-27).

Gross '991 and Gross '375 are silent with respect to the needle outlet exposed height of 0- 1 mm and the pharmacokinetic profile of the ID delivered drugs. Prausnitz teaches the use of needles with zero exposed height to deliver drugs into the skin. (col. 3, 11.27-38). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Prausnitz in the method of Gross '991 or Gross '375 in order to provide a known flow dynamic as desired from the end of the delivery needle. The zero exposed height needle as disclosed in Prausnitz is known to provide a substantially longitudinally directed flow as opposed to a more pronounced radially directed flow component as found in beveled needles when liquid exits the needle opening. One of ordinary skill in the art would know to select a particular exposed height needle dependent upon the desired flow delivery.

Autret, Puri, D'Antonio, and Srivastava each suggest a greater Cmax and bioavailability in intradermal injections as compared to subcutaneous injections (see Autret fig. 1; Puri, pgs. 2609-2610; D'Antonio col. 29, lines 3-23; and Srivastava col. 19, line 60 - col. 20, line 25). Autret discloses intradermal injection of a hormone resulting in a pharmacokinetic profile similar to subcutaneous delivery, but with a higher plasma level and bioavailability as assessed by Cmax and Tmax (fig. 1). The Merck Manual is cited here as evidence showing the various methods that bioavailability is assessed (see pg. 2560). Puri discloses that lower doses can be used with ID delivery than with SC delivery (pg. 2610). The ability to use lower doses is the practical result when a higher Cmax and bioavailability is achieved with equal dosages; whereby

the required Cmax and bioavailability is still achieved to treat the illness. As drug treatment efficacy depends on Cmax and bioavailability, one of ordinary skill in the art would recognize that when equal ID and SC dosages give higher Cmax and bioavailability via the ID route, then the ID dosage can be reduced to treat a patient. D'Antonio discusses experimental evidence in the prior art that indicate ID injections into the dermis are many times more powerful than SC injections. This allows greatly reduced dosages to be used (col. 29, 11.3-9). The ability to use lower dosages shows that a higher Cmax and bioavailability is achieved with ID over SC delivery. Srivastava describes a method of ID delivery of drug treatments where the ID injections typically required lower dosages than SC delivery (col. 20, 11.3-7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Autret, Puri, D'Antonio, or Srivastava in the drug delivery method of Gross '991 and Prausnitz or Gross '375 and Prausnitz to deliver effective drug treatments at particular pressures and flow rates to achieve higher Cmax and bioavailability with intradermal injection as compared to subcutaneous injection in order to effectively treat patients using lower dosages, thereby saving drug costs and inventories. Conserving drug inventories and lowering the costs'of drug treatments is desirable in the drug delivery field to maximize the treatment availability of the drug, and is something one of ordinary skill in the art is constantly looking to achieve.

Re claim 4 Gross '991 or Gross '375 does not disclose using multiple needles. Prausnitz teaches using multiple needles to achieve the desired drug injection flow (col. 3, line 27 - col. 4, line 7). It would have been obvious to one of ordinary, skill in the art at the time of the invention to use the teachings of Prausnitz in the method of Gross '991 or Gross '375 in order to achieve a larger drug delivery area and treatment zone.

Re claim 16 Gross '991 or Gross '375 does not disclose flow control by needle spacing or diameter. Prausnitz teaches using flow control by varying needle diameter or spacing (col. 4, 11. 3-7; col. 8, 11.54-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to

use the teachings of Prausnitz in the method of Gross '991 or Gross '375 in order to control flow parameters to vary injection rates and effects as desired.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-7, 10-16, 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 10 of copending Application No. 10/868482; claims 1, 2, 7, 8, 50 of copending Application No. 10/867908; claims 1-7, 9, 13, 16, 26, 28-30, 32, 35"-41, 46-48, 50, 52-54, 5.7, 59, and 62- 64 of copending Application No. 10/487485; claim 25 of copending Application No. 11/004780; claim 25 of copending Application No. 11/004778; claims 1-3, 8, 10-16 of copending Application No. 10/841992; claims 66 and 76 of copending Application No. 10/803735; claims 22-26, 29-31, 33 of copending Application No. 10/650039; claim 33 of copending Application No. 10/429973; claims 65, 71, 72, 75-77, 82 of copending Application No. 09/893746; claims 31, 32, 36, 37, 39, 49, 67, 73 of copending Application No. 10/028988; and claims 69, 72, 83-86, 88, 90, 100, 103 of copending Application No. 10/028989 in view of Gross' 991 or Gross' 375, and Prausnitz, Autret, Puri, D'Antonio, and Srivastava.

Claim 29 recites a method of drug administration by delivering a drug through a hollow needle into the intradermal compartment using a needle with its outlet depth and exposed height in the intradermal compartment and the needle having an exposed height of 0-1 mm so the delivered drug exhibits a pharmacokinetic profile similar to subcutaneous delivery but with a higher maximum plasma concentration and a higher bioavailability. Claims 8 and 10 of 10/868482 recite a method of administering a therapeutic agent into the intradermal compartment to achieve higher bioavailability as compared to another delivery route. These claims do not recite the use of a needle with an exposed height of 0-1 mm to deliver a drug intradermally to achieve higher Cmax along with higher bioavailability over delivering a drug subcutaneously. Gross '991 (3:40-41; 6:56 - 7:20) and Gross '375 teach a method of delivering insulin and hormones intradermally using a needle in a controlled manner (Gross '991; 4:10-35). Prausnitz teaches injecting a drug through multiple needles with a zero exposed height (c01.3, line 27 - col. 4, line 7). Autret, Puri, D'Antonio, and Srivastava each disclose achieving a greater Cmax and bioavailability via intradermal injections as compared to subcutaneous injections (see Autret fig. 1; Puri, pgs. 2609-2610; D'Antonio col. 29, lines 3-9; and Srivastava col. 19, line 60 - col. 20, line 25 as discussed above). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Autret, Purl, D'Antonio, Srivastava, Gross '991, Gross '375, and Prausnitz in the claimed method of claims 8 and 10 of Application Nos. 10/868482, in order to provide a known flow dynamic as desired from the end of delivery needles as a longitudinally directed flow and to effectively treat patients with lower drug costs resulting from using less drugs dosages and maintaining greater drug inventories.

The claims of the other applications listed above: claims 1, 2, 7, 8, 50 of copending Application No. 10/867908; claims 1-7, 9, 13, 16, 26, 28-30, 32, 35-41, 46-48, 50, 52- 54, 57, 59, and 62-64 of copending Application No. 10/487485; claim 25 of copending Application No. 11/004780; claim 25 of copending Application No. 11/004778; claims 1-3, 8, 10-16 of copending

Application No. 10/841992; claims 66 and 76 of copending Application No. 10/803735; Claims 22-26, 29-31, 33 of copending Application No. 10/650039; claim 33 of copending Application No. 10/429973; claims 65, 71, 72, 75-77, 82 of copending Application No. 09/893746; claims 31, 32, 36, 37, 39, 49, 67, 73 of copending Application NO. 10/028988; and claims 69, 72, 83-86, 88, 90, 100, 103 of copending Application No. 10/028989 recite similar methods as claims 8 and 10 of application 10/868482. All these claims are directed to delivery of drugs to the intradermal compartment to achieve greater absorption, Cmax, and/or bioavailability. All these claims in view of Gross '991 or Gross '375, and Prausnitz, Autret, Puri, D'Antonio, and Srivastava render claims 29, 2-7, and 10-16 obvious with similar reasoning as stated above with respect to Application 10/868482.

These are provisional obviousness-type double patenting rejections.

Response to Declarations and Arguments

Applicant argues that the cited references are silent with respect to elements (a) and (b), as listed on pg. 7, first full paragraph of remarks received 6/18/2007. The examiner disagrees and refers Applicant to discussion of needle configuration and placement in the intradermal compartment above.

Applicant argues that the prior art does not disclose delivery to the ID layer. The examiner disagrees and refers applicant to Gross '991 where the drug delivery is described "to the interior of the dermis" (col. 3, 11.38-40). Additionally Gross '375 discloses intradermal delivery depending on the condition treated (col. 6, 11.25-34) and that the needle tip is placed intradermally to accomplish the drug delivery (col. 5, 11.25- 29). Delivery to the intradermal layer is taken as directly stated - that the delivery results in delivering the drug into the ID layer, not outside of this layer, and delivery into the ID layer requires the needle outlet to be completely within the intradermal layer. One of ordinary skill in the art would find obvious that a statement of delivering to a location would require the needle outlet (depth and exposed height) to be within the desired location, so as to accomplish the desired delivery. If the needle

outlet depth and exposed height were not within the intradermal compartment, and Gross was describing a delivery to non-selective locations, Gross would have described his delivery as to the interface between the epidermis and dermis and the interior of the dermis and subcutaneously, rather than in the alternative.

Gross discloses the choice of delivering drugs to three distinct regions: the interface between the epidermis and the dermis, the interior of the dermis (i.e., intradermal compartment), or subcutaneously. The rejections above are based on the disclosure related to delivering to the intradermal compartment, as previously discussed. In this manner, Gross is particularly concerned with selective location of drug administration. Even if Gross did not disclose delivery solely to the ID layer it would have been obvious to one of ordinary skill in the art to deliver solely or completely to the ID layer because the delivery to different layers or depths to a patient is known to have different effects and selecting which location to deliver to from the limited number of depths (e.g. including epidermis, intradermal, or subcutaneous) would have been obvious to try.

Applicant argues that the references are silent to improved pharmacokinetics resulting from intradermal administration. The examiner disagrees and refers Applicant to discussion of pharmacokinetic effect of intradermal delivery above, particularly with respect to Cmax and bioavailability.

Applicant states that Autret does not recognize higher maximum plasma concentration and bioavailability. The examiner disagrees because the data presented by Autret shows a higher Cmax and a higher bioavailability as assessed by Cmax and Tmax (See fig. 1). The difference in Autret's characterization of their data and Applicant's characterization of their data appears to be based on differing statistical analysis. However, Applicant has not claimed any results with respect to a particular statistical significance. Applicant states that Autret does not recognize any difference between ID and SC deliveries. The examiner notes that in view of the document as a whole, and of the data point values, Autret's statements concerning no difference are directed to no statistically significant differences; and that the data clearly show a numerical difference. The statistical analysis applied to the experimental data

appears to determine what is a significant difference and Applicant has not claimed the difference between ID and SC to be different with respect to a particular statistical analysis.

Applicant's arguments regarding the prior art not showing both higher Cmax and higher AUC are not convincing because Applicant is arguing limitations that are not recited in the claims or are not the same scope of the claims. The claims recite an ID delivery method giving higher maximum plasma concentration and higher bioavailability, not AUC. The Merck Manual (cited above) states that there are several methods to assess bioavailability, particularly Cmax, Tmax, and AUC. Although AUC may be the most prevalent method to determine bioavailability it is not the sole method. Applicant's specification has not explicitly defined that bioavailability is calculated only by AUC in his invention. Using Cmax and Tmax Autret is seen to show higher bioavailability with ID delivery than SC delivery.

The role of pressure is not consistent in Applicant's arguments. Pressure is acknowledged as a critical feature in the first paragraph on pg. 7 of remarks received 1/06/05, but then Applicant states "Nor is the absolute value at which pressure is applied critical to the claimed invention." (3rd paragraph of remarks received 1/06/05). Since it is obvious to one of ordinary skill in the art that pressure values determine the flow rate one would view it as a critical feature of the claimed method. Applicant's remarks submitted 10/7/05 address the critical and non\- critical nature of pressure in his method, but these remarks do not further clarify the issue. Applicant's remarks that application of the correct amount of pressure is critical, but the absolute value of the pressure used is not critical are inconsistent. The absolute value of pressure used is the amount of pressure applied to deliver the drug at a desired rate, and since the value is the amount applied, either both are critical or both are not critical. Furthermore, Applicant's disclosure does not provide any guidance at which pressures are required to achieve the claimed method. Applicant merely invites the skilled artisan to experiment to determine pressure on their own.

Applicant arguments that Puri and D'Antonio are not concerned with drugs are not convincing. Applicant has not explicitly defined drugs in the specification to exclude vaccines. Additionally, vaccines such as cancer vaccines are both drugs for treatment (therapeutic vaccines) as well as vaccines to prevent development of cancer (prophylactic vaccine). The prior art discloses the desirability of injecting drugs and vaccines into the intradermal layer.

Applicant argues that D'Antonio is not concerned with injection of drugs or ID delivery, but focuses on intramuscular injections. This position is not convincing because although D'Antonio discusses intramuscular injections, the benefits of ID delivery over that of intramuscular and subcutaneous delivery is clearly stated at 29:3-9. D'Antonio also states that his invention concerns hypodermic fluid injections for medical treatment for a patient 1:15-17, 22:11-20 (i.e., drug administration). D'Antonio and Puri are cited to show the prior art recognition that delivery to the ID compartment gives a greater Cmax than SC delivery as suggested in the results that a lower dose of drug can be used with ID delivery as compared to SC delivery.

Applicant argues that Autret, Puri, D'Antonio, and Srivastava are not concerned with insulin delivery. The examiner points out that these references were cited for disclosure of intradermal delivery achieving higher Cmax and bioavailability. Gross discloses insulin delivery to the intradermal compartment. The prior art recognizes the benefits of intradermal delivery of drugs over subcutaneous delivery with respect to Cmax and bioavailability.

The declaration under 37 CFR 1.132 filed 6/18/2007 is insufficient to overcome the rejection of claims 2-4, 10-13, 15, 16, and 29 based upon the rejection under 35 U.S.C. 103(a) as being unpatentable over GROSS (US Patent No. 5,848,991) or GROSS (US Patent No. 5,807,375) in view of PRAUSNITZ (US Patent No. 6,611,707), AUTRET,, PURl (An investigation of the intradermal route as an effective means of immunization for microparticulate vaccine delivery systems), D'Antonio et al. (US Patent No. 6,056,716), SRIVASTAVA (US Patent No. 6,007,821), and The Merck Manual of Diagnosis and

Therapy (17th ed.) (1999) as set forth in the last Office action because: the declaration concludes that Gross does not describe a needle whose depth and exposed height are located within the intradermal compartment after analyzing example 1 disclosed in Gross. The examiner finds this insufficient because Gross discloses the administration of drugs to three distinct locations, as discussed above. A practitioner of the method disclosed in Gross would need to decide into which location he desires to administer a drug. Example 1 does not state into which region the drug was delivered. Applicant's assumption that this example is directed to intradermal delivery is unfounded. Additionally, Applicant's analysis of the results of example 1 appear to show that it is directed to one of the other delivery locations disclosed by Gross. The examiner had addressed this issue in the office action mailed 6/15/2004, pg. 5, last paragraph, where multiple locations of drug delivery are disclosed by Gross, but is silent on which location applies to the examples.

Conclusion

All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witczak/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767